

REMARKS

The amendments to the claims do not add new matter. Dependent claim 26 has been cancelled and its limitation that “said second end for engaging a driving and securing device is **slotted**” is incorporated into each of independent claims 11, 20 and 23. Accordingly, this amendment does not add new matter or require any additional consideration by the Patent Office than was already considered for claim 26 (now cancelled). The further amendment to claim 23, interchanges the limitations between the “first end” and the “second end” so that the first end and the second end now have limitations that parallel and conform to the limitations recited in claims 11 and 20 . This latter amendment eliminates any confusion between the claims.

Claim 11, as amended, is directed to the embodiment described in the specification at e.g., page 9, lines 10-23, and exemplified in FIGs 10A-10B. The preamble of claim 11 uses the term “assembled” which more accurately describes the embodiment being claimed. Claim 11, which has been amended at line 2 to recite “adjacent vertebrae,” has support for the term “adjacent vertebrae” later in the claim. In conformity with the description of the juxtaposition of the “first section” and the “second section” of FIGs 10A and 10B, the references to the “first” end and the “second” end of the elongated body have been switched.

Claim 12 was amended by deleting some of the alternatives. Claim 13, which recites that the two or more threaded sections of cortical bone have “joining holes” for insertion of the pins, is supported throughout the specification, including FIG 10A where they are shown but not numbered. Claims 14, 16, and 17-19 have been clarified.

Claim 20 has been amended to claim the specific embodiment of FIG 10A, having “two pins” which is shown as assembled in FIG 10B. In conformity with the description of the juxtaposition of the “first section” and the “second section” of FIGs 10A and 10B, the references to the “first” end and the “second” end of the elongated body have been switched.

Claims 22 and 23 deleted some extraneous language.

New claim 25, which recites that the “two pins” are “two cortical bone pins,” is supported throughout the specification, including at page 9, line 14 (“cortical bone”).

New claim 26, which recites that the second end of the elongated body is “slotted,” is supported by the disclosure at page 9, line 16 (“The second section has a slot 1015 formed thereon . . .”).

Independent claim 27, which is directed to an “assembled threaded implant for implantation between adjacent vertebrae in the spine of a patient” is supported by FIG. 10; the specification at page 9, line 11 (“composed of two or more sections”), and the same support as for claim 11.

Claim 28, which is directed to the implant of claim 27, having “two” threaded and continuously tapered sections of cortical bone, is supported by the specification at FIG. 10; and at page 9, line 11 (“composed of two or more sections”). Claim 29, which is directed to the implant of claim 27, wherein said “second end includes a slot formed thereon,” is supported throughout the specification, including at page 9, line 15 (“The second end has a slot 1015 formed thereon for engaging a securing device.”). Claim 30, which is directed to the implant of claim 27, “wherein said second end includes a square driver,” is supported throughout the specification, including at page 8, line 10 (“The peg acts as a driver. . .”) and at page 8, line 14 (“alternatives for the shape of the peg, e.g., square and hexagonal.”). Claim 31, which is directed to the implant of claim 27, “wherein said second end includes a hexagonal driver,” is supported throughout the specification, including at page 8, line 10 (“The peg acts as a driver. . .”) and at page 8, line 14 (“alternatives for the shape of the peg, e.g., square and hexagonal.”). Claim 32, which is directed to the implant of claim 27, wherein said second end includes “two or more pinch cut outs,” is supported throughout the specification, including at page 8, lines 28 (“comprises **two or more pinch cut outs** 905 from the edge of the wider of the two ends. . . .”); emphasis added in bold. Claim 33, which is directed to the implant of claim 27, “wherein said second end includes “two pinch cut outs,” is supported by throughout the specification, including at page 8, lines 28 (“comprises **two or more pinch cut outs** 905 from the edge of the wider of the two ends. . . .”); emphasis added in bold.

For all these reasons, the amendments to the claims do not add new matter.

Summary of the Bases for Rejection

Claim 19 is rejected under 35 U.S.C. § 101 for allegedly being drawn to non-statutory subject matter.

Claims 11-14, 16-23 and 25-26 are rejected under 35 U.S.C. § 103(a), as being allegedly unpatentable over U.S. Patent No. 6,200,347 (“Anderson”) in view of U.S. Patent No. 6,261,586 (“McKay”).

The Applicants will address each of these bases for rejection in Sections I-II, respectively, which follow.

I. 35 U.S.C. § 101

Claim 19 is rejected under 35 U.S.C. § 101 for allegedly being drawn to non-statutory subject matter. [Official Action at page 2] Specifically, the Patent Office contends that in claim 19, line 2, Applicant positively recites part of a human, *i.e.*, “said cortical bone is **human**” and that “claim 19 includes **a human** [a noun] within its scope and are [sic “is”] nonstatutory.” [Official Action at page 2; emphasis added in bold.] The Patent Office then goes on to say that “A claim directed to or including within its scope **a human** [a noun] is not considered to be patentable subject matter under 35 U.S.C. § 101.” [Official Action at page 2; emphasis added in bold.] The Applicants respectfully disagree.

The Patent Office misinterprets § 101 or Applicants’ claim as falling under the prohibition of the statute. In particular, the quotation relied upon by the Patent Office from Applicants’ claim 19 is a partial quotation taken out of context, such that the word “human” appears to be a noun (object) rather than an adjective (source or type). More specifically, the Patent Office states that claim 19 recites:

“said cortical bone is **human** [noun]”

However, when the relevant portion of claim 19 is recited in context, it actually reflects that the word “human” is used as an adjective in claim 19 and fails to fall under the prohibition of a noun:

“said cortical bone is **human** [adjective] allograft bone”

Moreover, prior to the amendment of claim 19 in response to the Official Action of 01/05/04, claim 19 recited the word “human” as the same adjective as now rejected:

“formed substantially from **human** [adjective], allograft cortical bone . . .”

Thus, there is no reason why this **new** basis for rejection could not have been made prior to the final rejection. If the Patent Office insists on maintaining this basis for rejection, then the finality of the present Official Action should be removed so that the Applicants could submit **evidence** in response to this new basis for rejection.

Separately, the Applicant went to the USPTO’s official website and searched the term “human” in the claims. The Applicants received 52,807 hits, i.e., recitations of the word “human” in the claims. Attached hereto as Exhibit A is a copy of the first hits. The titles of the patents in these hits reflect that the word “human” is acceptable when used as an adjective. As an example, the Applicants cite to hit number 26, U.S. Pat. 6,825,322, which issued 11/30/04, entitled “**Human** N-methyl-D-aspartate receptor **subunits**, nucleic acids encoding same and uses therefor.” Consistent with its title, claim 2 of the 1 patent is directed to the following “human. . . subunit”:

2. A substantially pure **human** N-methyl-D-aspartate receptor **subunit** comprising the sequence of amino acids set forth in SEQ ID NO: 56.

[Exhibit B: Claims of U.S. Pat. 6,825,322; emphasis added in bold.]

Thus, for these 52,807 reasons, and the other reasons discussed above, this basis for rejection should be withdrawn, or the finality of this rejection should be withdrawn.

II. 35 U.S.C. § 103(a) over Anderson in view of McKay

A. The Combination of Anderson and McKay Fail to Make a *prima facie* Case of Obviousness Against the Invention As Claimed

Claims 11-14, 16-23 and 25-26 are rejected under 35 U.S.C. § 103(a), as being allegedly unpatentable over U.S. Patent No. 6,200,347 (“Anderson”) in view of U.S. Patent No. 6,261,586 (“McKay”). According to the Patent Office, “[w]ith respect to

claims 11, 20, Anderson et al discloses an assembled implant, as best seen in the figures, for implantation between adjacent vertebrae in the spine of a patient comprising two or more sections of cortical bone; as best seen in FIGS. 1-10, that are **joined in tandem** by a pin (7, 9, 13) interconnecting the section [sic “sections”] to form an **elongated body** having a first end for initially engaging vertebrae and a **second end for engaging a driving and securing device**,¹ therein the elongated body comprises a **continuously tapered surface** from about 5mm to about 25 mm in length; as set forth in column 23, lines 1-67, column 31, lines 1-22 and as best seen in the figures.” [Official Action at page 3; emphasis added in bold.] The Patent Office admits that “Anderson **did not teach of threads** on the surface of an implant to secure the implant in the vertebrae.” [Official Action at page 3; emphasis added in bold.] To make up for this deficiency, the Patent Office cites to McKay for disclosing “threads on the surface of the implant. . . .” [Official Action at page 3.] The Patent Office then concludes that “it would have been obvious to one having ordinary skill in the art at the time the invention was made to replace the serrations or saw-tooth pattern of Anderson et al. with the threads of McKay to secure the implant in the vertebrae.” [Official Action at page 3.] The Applicants respectfully disagree.

As an initial matter, the Patent Office fails to note the difference between the common ordinary everyday words “tandem,” abreast” and “stacked.” Each is important, not only from a structural perspective, but also because of the differences in forces that are placed on the pins in each of those embodiments. The ordinary meaning of the term “tandem” is that something is connected head to tail- **one behind the another**, whereas “abreast” means “**side by side**”:

tandem – one behind another, in single file

[Exhibit C: Webster’s New World Dictionary, Second College Edition, Guralink, Ed., Prentice Hall Press, Cleveland OH, at page 1453; emphasis added in bold.]

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¹ It is respectfully submitted that no implant of Anderson shows the presence of an end that is modified for an insertion tool. If the Examiner thinks otherwise, the Applicants respectfully request that he point out the exact Figure or location of such a disclosure. The word “tool” is only associated with “milling tool” and “dremel tool” for surface features.

abreast – side by side, as in going or facing forward

[Exhibit C: Webster's New World Dictionary, Second College Edition, Guralink, Ed., Prentice Hall Press, Cleveland OH, at page 4; emphasis added in bold.]

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stacked – any somewhat **orderly pile or heap**, as of boxes, books, poker chips, etc.

[Exhibit C: Webster's New World Dictionary, Second College Edition, Guralink, Ed., Prentice Hall Press, Cleveland OH, at page 1384; emphasis added in bold.]

In relation to Anderson, the Patent Office contends that the two or more sections of cortical bone are “**joined in tandem**” by a pin (7, 9, 13) interconnecting the section [sic “sections”] to form an **elongated body**. . . .”

However, referring to FIGS. 1-10 of Anderson, it can be seen that all of the sections of cortical bone are placed “**abreast**” of one another, and **not “in tandem.”** In particular, Anderson refers to his bone segments that are joined abreast as “plate-like bones.” [Anderson at col. 6, lines 34-36 (“The invention also provides a composite bone graft where the one or more through-holes are disposed perpendicular to interfaces of **plate-like bones** of the graft unit”); emphasis added in bold.] In viewing the bone grafts of Anderson, it is important to remember that due to the location of the spinal column at the posterior end of the vertebrae, the spinal implants of Anderson (and Applicants) are inserted between the patient’s vertebrae from the anterior (front side) of the patient and pushed back toward the posterior (rear) of the patient. [Anderson at col. 2, lines 13-16 (“The present composite bone grafts can be used as structural grafts **placed posteriorly** in the spine as interbody grafts or as strut grafts spanning multiple segments.”); emphasis added in bold.] The implants are constructed with this orientation in mind and are referred to in the art as having a posterior side and an anterior side which corresponds to the anterior and posterior positions in the patient. FIG. 3, which is the posterior orientation of FIGS. 1 and 2, shows the three segments of bone joined **abreast** in a **side-by-side** orientating as opposed to a **tandem** (longitudinal) **head-to-tail** orientation. [Anderson at

col. 8, lines 55-56 (FIG. 3 illustrates a cross-section posterior view of the trapezoid wedge composite bone graft of FIG. 2.”)] Comparing FIG. 3 to FIGS. 2 and 4, the face of FIG. 3 is shorter than the anterior face of FIG. 4, and the rows of teeth in FIG. 2 are shown as running parallel to the anterior (FIG. 4) and posterior (FIG. 3) faces of the implant of FIG. 2. Moreover, the joining of the three bodies shown in FIGS. 1-4 forms a **wider body** as opposed to “form[ing] an elongated body” as recited in each of independent claims 11, 20 and 23.

The Applicants respectfully submit that the above analysis applies equally to the implants of FIGS. 5-10 that are relied upon by the Patent Office. Specifically, FIGS. 5 (top) and 6 (perspective) are two different views of the implant of FIG. 2 as discussed above. [Anderson at col. 8, lines 63-67.] FIG. 6 shows the posterior end of the implant of FIG. 2 with the three bone segments (10a, 10b and 10c) shown in a side-by side orientation. FIGS. 7 and 8 are different views of the same slideable implant. The slideable implant of FIGS. 7 and 8 are connected abreast (side-to-side) of one another, and not “**in tandem**” as recited in the Applicant’s claims. Moreover, the implants of FIGS. 7 and 8, which are not tapered, when combined with the untapered implants of McKay could not teach or suggest the tapered implants of the Applicants’ claims. Separately, FIG. 9 is merely the untapered implant of FIG. 8, composed of three side-by-side bone segments without any surface features whatsoever. Finally, FIG. 10 is a replacement for a “**cloward dowel**” wherein the plates are positioned side-by side and connected by a **single central bone pin**. [Anderson at col. 20, lines 47-53 (“FIG. 10 illustrates a preferred composite bone graft 25 including a plurality of cortical bone portions including a first cortical bone portion 26, a second cortical bone portion 27, a third cortical bone portion 28, a forth cortical bone portion 29, a fifth cortical bone portion 30, and a **single cortical bone pin** 31 inserted in through-hole 32. This graft can be used in place of the traditional **cloward dowel**.”); emphasis added in bold.]

The other figures of Anderson either show wedge-shaped implants (FIGS. 12, 13A, 27, 28, 29, 30, 31A-B, 33A-C, 34, 36A, 39, 41, wherein the bone plates are aligned “abreast,” or block-shaped implants (FIGS. 32A-C, 42), wherein the bone plates are aligned “abreast,” or implants that are composed of “stacked” plates (FIGS. 14A-C, 15, 35A, 37, 38, 40B, 43 and 44) where the plates are superimposed upon one another.

The Patent Office responded to the above arguments in the Advisory Action of 01/25/05. As support for Anderson's teaching of "tandem (longitudinal) head to tail orientation, the Patent Office, directed the Applicants' attention to Anderson at col. 2, lines 60-61 as recited below:

. . . the first, second and third bone portions are disposed one **on** the other (i.e., **layered**) to form a graft unit;

[Anderson at col. 2, lines 60-61; emphasis added in bold.]

However, the above statement by Anderson recites the common everyday words "on" and "layered". Given their ordinary meaning, both the words "**on**" and "**layered**" require something that is **above** or **upon** or **lays on** something else as in a **layer cake**:

on 1. in a position **above**, but in contact with and **supported by, upon**.

[Exhibit C: Webster's New World Dictionary, Second College Edition, Guralink, Ed., Prentice Hall Press, Cleveland OH, at page 993; emphasis added in bold.]

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layer – a person or thing that **lays**.

[Exhibit C: Webster's New World Dictionary, Second College Edition, Guralink, Ed., Prentice Hall Press, Cleveland OH, at page 800; emphasis added in bold.]

Thus, Anderson, discloses a "layered" configuration wherein sections are stacked one upon another, such that "one" layer is "**above**" and "**supported by, upon**" the other. A "layer" has a thickness that is smaller than its length or width. When a layer is stacked, it is stacked along its thinnest dimension. FIGS. 1-10 of Anderson are totally consistent with this interpretation. FIG 11B of Anderson shows how the implants of FIGS. 1-10 are assembled. In particular, while stacked **laying flat** in a **layered form**, the layers are drilled; and then while stacked **laying flat** in a **layered form**, the **pins** are driven into the layers. In contrast, the Applicants' bone portions are not ever layered along their shortest dimension. For these reasons, Anderson does not teach or suggest the tandem (head to tail)

configuration that characterizes the Applicants' assembled implant. By analogy, the assembled implants of the Applicants' invention are joined or assembled in a standing (head to tail) position as opposed to a layered (back to belly) position of Anderson.

Finally, in the Applicants' implant "all longitudinal surfaces are continuously tapered and threaded. While the Patent Office contends that Anderson discloses an elongated body that comprises a continuous tapered surface, Anderson only teaches an implant that at best, is tapered along only two of its four sides (longitudinal surfaces). Thus, Anderson never teaches or suggests an implant that is continuously tapered on all longitudinal surfaces.

McKay, which is cited for disclosing "threads on the surface of the implant. . ." [Official Action at page 3], does not make up for the lack of tandem alignment in Anderson as pointed out above. McKay does not make up for the deficiency in Anderson by teaching an implant that is continuously tapered on all longitudinal surfaces. Thus, the combination of Anderson and McKay fails to teach or suggest tandem alignment of bone segments, or an implant that is continuously tapered on all longitudinal surfaces, as now claimed.

Moreover, when Anderson **layered** circular plates together, he used a single bone pin along which the individual plates could rotate. When McKay made a threaded dowel (lacking a continuous taper), he used a single block of bone and no bone pins. Neither Anderson nor McKay teach or suggest an implant that is continuously tapered and threaded on all longitudinal sides, and that uses a plurality of "pins" to or one that is assembled from pieces "in tandem." For these reasons, the combination of Anderson and McKay would not make a *prima facie* case of obviousness.

B. The Patent Office Failed to Address the Problem Solved by the Present Invention

Any obviousness analysis requires that the Patent Office consider the problem solved by the inventors. *See In re Wright*, 6 USPQ2d 1959, 1961 (Fed. Cir. 1988) (the particular problem facing the inventor must be considered in determining obviousness."). In the present analysis, the Patent Office has failed to address the problem solved by the Applicants. Specifically, the Applicants discovered that cortical bone "pins"

could withstand the torsional (twisting) stress applied to their narrow cross-sections when used to connect two segments of a cortical bone screw “in tandem.” This was neither taught nor suggested by the cited art. Anderson only taught the use of bone pins for aligning bone segments that were **layered** on one another. Anderson’s layered bone segments then were rotated 90° and inserted in their “abreast” alignment. No torsional strain was ever applied to these aligning pins because the wedge shaped implants, which had multiple pins were never twisted nor intended to be twisted. Specifically, Anderson states that his implants “**do not shift, extrude, or rotate; after implantation**”:

The invention solves the problem of graft failure by providing a composite bone graft which can be appropriately sized for any application out of for example, strong cortical bone; promotes the ingrowth of patient bone at an implantation site by promoting osteoinductivity and cellularization; provides added stability and mechanical strength; and **does not shift, extrude or rotate; after implantation.**

[Anderson at col. 1, line 67 to col. 2, line 6; emphasis added.]

In contrast, the very act of implanting, adjusting or removing the Applicants’ implants requires “**rotation**” of the implant and the connecting pins. The rotation causes all of the torsional stress from the second end of the Applicants’ implant to be transferred to the tapered first end via the pins interconnecting the first and second ends “in tandem.” The secondary reference, McKay, does not make up for this deficiency. In particular, all of the implants of McKay were made from a single block of cortical bone. Hence, there were no bone pins whatsoever. Moreover, there was no teaching or **suggestion** that cortical bone pins could be sufficient to support the torsional strain that was to be applied to a rotated and threaded implant for insertion between adjacent vertebrae.

When Anderson **layered** circular plates together, he used a single bone pin along which the individual plates could rotate. When McKay made a threaded dowel (lacking a continuous taper), he used a single block of bone and no bone pins. For all these reasons, there was no teaching or **suggestion** that cortical bone pins could support the torsional strain that was applied to the body of a threaded implant made of solid bone.

Thus, the combination of Anderson over McKay failed to address the problem solved by the Applicants or to render the Applicants' solution or invention obvious. *See In re Wright*, 6 USPQ2d at 1961 ("it is error to focus 'solely on the product created, rather than on the obviousness or nonobviousness of its creation.'"). *See In re Wright*, 6 USPQ2d at 1961 ("appellant's problem' and the prior art 'present different problems requiring different solutions"). More importantly, there was no suggestion to do what the Applicant's had done or any recognition of the problem to be solved, or that Applicants' solution would work.

For all these reasons, any *prima facie* case of obviousness against claims 11-14, 16-23 and 25-26 has been rebutted.

CONCLUSION

Claims 11-14, 16-20, 22-23 and 25-26 stand rejected. Claim 26 has been cancelled by amendment herein after its limitation was incorporated into each of independent claims 11, 20 and 23. Claims 27-33 have been added by amendment herein. Accordingly, only claims 11-14, 16-20, 22-23, 25 and 27-33 are pending.

In view of the arguments herein, the rejection of claim 19 under 35 U.S.C. § 101 for use of the adjective “human” should be withdrawn for being inappropriate, or the finality of the rejection withdrawn because the rejection over the same phrase, “human . . . bone,” could have been previously made by the Patent Office but was not. In view of the amendments and arguments provided herein, all bases for rejection of claims 11-14, 16-20, 22-23 and 25 under 35 U.S.C. § 103(a) for allegedly being obvious over Anderson in view of McKay have been rebutted.

For all these reasons, claims 11-14, 16-20, 22-23, 25 and 27-33 are in condition for allowance.

Respectfully submitted,

McANDREWS, HELD & MALLOY, LTD.

By:



Donald J. Pochopien
Registration No. 32,167
Attorney for Applicants
500 West Madison Street
34th Floor
Chicago, Illinois 60661
(312) 775-8133

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